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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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LI, QIAN J

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1632

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/003,669	BROYLES ET AL.
	Examiner Q. Janice Li	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3,11-13,19 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3,11-13,19 and 22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 November 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>15</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9,11</u> | 6) <input checked="" type="checkbox"/> Other: <i>Notice to Comply</i> |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in Paper No. 12, and species election drawn to delivery of exogenous ferritin-H protein to globin-producing cell in Paper Nos. 14 & 15, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 2, 4-10, 14-18, 20, 21, and 23 have been canceled, and claims 1 and 22 have been amended. Election was made **without** traverse in Paper No. 14.

Claims 1, 3, 11-13, 19, and 22 are pending and under current examination.

Specification

The specification contains sequence disclosures (fig. 4A, fig. 5) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. Applicant must provide a paper copy and a computer readable copy of the Sequence Listing and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or

1.821(g) or 1.825(b) or 1.825(d). A full response to this Office action must include a complete response to the requirement for a new Sequence Listing.

Claim Rejections

Claim 11 is objected to because the claim as written encompasses multiple inventions. Claim 11 broadly encompasses many different means of suppressing the expression of adult beta-globin genes in globin-producing cells, such as introducing into the cells a nucleic acid expressing ferritin-H (group IV) or inducing the expression of endogenous ferritin-H (group II). Once applicants elected an invention for examination in this application, the claims should be amended so that they read on only the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 11-13, 19, and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the

application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings, or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement*; Federal Register/ Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claims are drawn to ferritin-H or *derivative thereof*, and methods of using such. The specification fails to disclose *any chemical structure* that would be identified as derivatives of ferritin-H and which has the function of full-length ferritin-H, i.e. represses adult β -globin promoter. Thus, the claimed invention has not been set forth in terms of distinguishing characteristics as evidenced by other descriptions of the invention for the claimed derivatives.

Claim 22 recites, “a cell specific targeting *ligand* for introduction into globin producing cells”. However, the specification fails to teach any ligand(s) that is specific for globin-producing cell but not present in other cell types, so that it could be used specifically targeting the globin-producing cell.

An adequate written description of a substance (e.g. ferritin-H derivatives or cell-specific ligands) requires more than a mere statement that it is part of the invention; what is required is a description of the substance itself. It is not sufficient to define material solely by its principal biological property, i.e. **ligand for introduction into**

globin-producing cells, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any ligand with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all ligands that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to the method claims, adequate description of the methods first requires an adequate description of the materials, i.e. specific chemical structures of the ligands, which provide the means for practicing the invention. Therefore, the specification does not provide an adequate written description of the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To the extent that the claimed methods and composition are not adequately described in the instant disclosure, claims 1, 3, 11-13, 19, and 22 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been adequately described.

These claims are drawn to derivatives of ferritin-H, however, as indicated *supra* in the written description section, the specification fails to provide an adequate description for the genus of molecules encompassed by the claims. Since the disclosure fails to describe the common attributes or characteristics that identify members of the claimed genus, ferritin-H alone is insufficient to describe the genus. Particularly, ferritin-H is a DNA binding protein that binds specific region of a promoter, and represses the activity of the promoter, thus, the structure of the protein affects its biological activity, i.e. proper dimerization and interaction with transcriptional binding region of the promoter. *Bowie et al* (Science 1990 Mar; 247:1306-10) teach certain position in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or none at all (page 1306, column 2). Thus, the function of the ferritin-H may be abolished with substitution of only one amino acid of the peptide in a crucial position. The specification fails to teach exactly what modifications and variations can be tolerated in this protein and still allow proper ferritin-H function, accordingly fails to provide an enabling disclosure commensurate with the scope of the claims. *Rudinger* (Peptide Hormones 1976; June; pages 1-7) teaches the relationship of sequence components and the peptide hormone function "THE SIGNIFICANCE OF PARTICULAR AMINO ACIDS AND SEQUENCES FOR DIFFERENT ASPECTS OF BIOLOGICAL ACTIVITY CANNOT BE PREDICTED A PRIORI BUT MUST BE DETERMINED FROM CASE TO CASE BY PAINSTAKING EXPERIMENTAL STUDY." (last paragraph of text on page 6). Determination of the effects of particular modifications is not predictable until they are actually made and used, hence resulting in a trial and error situation. Therefore, the general knowledge and levels of

skill in the art do not supplement the omitted description, because specific, not general guidance is what is needed. One cannot extrapolate the teachings of the specification to the scope of the claims because the skilled artisan cannot envision the detailed structure of ferritin-H derivatives encompassed by these claims and whether they can serve as a functional repressor for β -globin promoter. Therefore, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation as it is broadly claimed.

Claims 1, 3, 11-13, 19, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the scope of the claims relative to the state of the art, and whether sufficient amount of direction or guidance are

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provided in the specification to enable one of skill in the art to practice the claimed invention.

Claims 1, 3, 11-13, 19 are directed to a therapeutic method for suppressing diseases caused or enhanced by effects of intracellular iron mismanagement, particularly sickle cell disease, comprising introducing exogenous ferritin-H or derivative thereof into globin-producing cells so that the intracellular amount of ferritin-H or a derivative thereof is increased, and the expression of adult β -globin genes is suppressed, wherein the ferritin-H is introduced for example by ligand targeted delivery or fusing the globin-producing cells with liposomal construct containing ferritin-H. Claim 22 is drawn to a pharmaceutical composition comprising ferritin-H or a derivative thereof, and a globin-producing cell specific targeting ligand.

These claims clearly read on a therapeutic method and composition for treating globin-producing cell associated disease. With respect to claim breadth, the standard under 35 U.S.C. §112, first paragraph, entails the determination of what the claims recite and what the claims mean as a whole. "WHEN A COMPOUND OR COMPOSITION CLAIM IS LIMITED BY A PARTICULAR USE, ENABLEMENT OF THAT CLAIM SHOULD BE EVALUATED BASED ON THAT USE". (MPEP 2164.01c) When analyzing the enabled scope of the claims, the intended use is to be taken into account because the claims are to be given their broadest reasonable interpretation that is consistent with the specification. "A pharmaceutical composition" is defined as a composition for therapeutic use, to prevent, alleviate, treat, or cure a disease within the animal to which the substance is administered, therefore, will be evaluated by the standard.

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In view of the guidance provided, the specification teaches that the *nuclear ferritin-H* is a gene regulatory protein in human cells, it binds to a specific DNA sequence centrally placed in the promoter of the human β -globin gene and represses transcription of this gene in transfected cells. The specification prophetically concludes, "Thus, a ferritin-H gene or peptide targeted to the correct cells offers a cure for sickle cell disease in which the β -globin gene is mutated, as well as other genetic diseases where there is mismanagement of iron" (Specification, page 23, 1st paragraph). The specification reviews diseases associated with cellular iron mismanagement, such as Sickle cell disease, neurodegenerative disease, skin cancer, and atherosclerosis. The specification teaches, "The phenotype of the effected cell can also be altered by delivering the expressed peptide itself (i.e., ferritin), or part thereof, directly into the diseased cell or to the cell before it exhibits the disease phenotype" (Specification, page 23, lines 18-19). Regarding peptide delivery, the specification teaches generally, for large protein, using liposome capsules and ligand directed at a specific cell surface receptor (Specification, paragraph bridging pages 19 & 20). In working examples, the specification teaches that the ferritin-H represses the transcriptional activity of β -globin promoter in a transient co-transfection assay with plasmid vectors expressing ferritin and reporter gene, wherein the expression level of a reporter β -CAT was repressed by over 60% in cultivated CV-1 cells in the presence of an expression clone of human ferritin-H (Specification, Section bridging pages 40-41).

However, the specification fails to teach the mode and efficiency of delivering intracellularly the ferritin-H peptide either *in vivo*, or *in vitro*. The claims require targeted

delivery of ferritin-H into globin-producing cells. For *in vivo* cell targeting, the specification fails to teach any strategy other than using a ligand. However, the specification fails to teach any ligand specific for globin-producing cells. Assuming the ligand is well known in the art, then the ligand-ferritin-H has to be delivered to the nuclear compartment of the cell, and the common knowledge is that it is difficult to deliver such exogenous protein to cell nucleus, it is unpredictable, and the specification fails to teach how the ligand-linked exogenous ferritin-H can sufficiently pass through both the cellular and cytoplasmic membrane barriers to reach the nucleus. The ferritin-H is not a small protein, and when it is linked with a targeting ligand, the size of the recombinant protein would increase substantially; the specification is completely silent regarding the mode and efficiency of delivering such a recombinant protein, whether the macromolecule could efficiently targeting the globin-producing cells and efficiently entering the nuclear compartment of the cell. Assuming the macromolecule successfully entered the nucleus, the specification fails to teach how to construct such a ligand-ferritin recombinant protein so that the ligand does not interfere with the DNA-binding function of the ferritin-H.

Claims 3 and 13 call for fusing liposomal with globin-producing cells, however, the specification fails to teach how to achieve such *in vivo*. Moreover, the specification fails to teach the correlation between the observed transient molecular changes in *ex vivo* cultivated cells and phenotype changes in affected cells, particularly the long term effect on the phenotype of the cell since the Sickle cell disease is a chronic one. The specification fails to teach whether the *ex vivo* effects correlate well with the *in vivo*

effect such that a therapeutic effect could be achieved. Applicants are reminded that the ex vivo condition is a simplified model for cellular biochemistry, while the in vivo environment is much more complex, involving interactions of multiple intra- and extra cellular elements, thus, the scope of the support in the specification (a cell culture assay) does not correlate with the scope of the claims (a method of in vivo treatment).

It is also noted that the preamble of claim 1 is drawn to treating any disease associated with intracellular iron mismanagement whereas the ferritin-H is introduced only to globin-producing cells. The specification fails to teach any other disease associated with globin-producing cells beyond Sickle cell disease. Thus, the specification fails to provide an enabling disclosure commensurate with the scope of the claims.

Turning to the state of the art, the art is silent with regard to treating diseases with ferritin-H. Taking Sickle cell disease as an example, *Mankad* (Pediatric Pathol Mol Med 2001;20:1-13) teaches, at a post-filing date, that the molecular lesion in the hemoglobin and the abnormality in the beta globin gene were identified more than fifty years ago. It was hoped that a “cure” or a “satisfactory treatment” would soon follow. However, although decades of research improved our understanding of the pathophysiology of sickle cell disease, the treatment strategy is still under development, multiple treatment regimen targeting different stages and mechanisms of the disease development is required, and yet to become a reality (See particularly the first section of the article). Apparently, even at the post-filing date, ferritin-H has not yet entered the picture as a potential or well accepted therapeutic strategy. In fact, the prior art of record

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teaches that over-expressing the ferritin-H subunit in cultured erythroid cells could bring positive impact on iron management of the cell. For example, *Picard et al* (Blood 1996;87:2057-64, IDS) teach that ferritin-H overexpression downregulates the synthesis of the endogenous ferritin, increases the RNA binding activity of IRP, decrease β -globin mRNA accumulation, whereby the incorporation of 2-C¹⁴glycine into heme was reduced by 20-30%. However, the art is silent with regard to correlating the basic research finding with the clinical benefit, whether the 20-30% reduction in heme synthesis is sufficient to see a clinical benefit. A post-filing publication by the inventors (*Broyles et al*, PNAS 2001 July;98:9145-50, IDS) also reported repression of β -globin promoter activity by nuclear ferritin using ferritin-H cotransfection assays, but was silent with regard to treating diseases. Obviously, the art of record recognize the intracellular effect of delivering exogenous ferritin-H to iron distribution and metabolism *in vitro* but has not been able to translate such *ex vivo* finding to clinical benefit, and the delivery of ferritin-H was only practiced with the delivery of a *nucleic acid* expressing ferritin-H *ex vivo* to cultivated cells.

With regard to intracellular delivery of a protein, *Buckel* (Trends Pharmacol Sci 1996;17:450-6), while acknowledges the great advantage of using natural proteins for therapy, teaches, "THE PROBLEM IS, HOWEVER, THAT PROTEINS HAVE TO BE ADMINISTERED FROM OUTSIDE THE BODY FOR THERAPEUTIC PURPOSES. TO THIS EXTENT, THEY ARE AT A CONSIDERABLE DISADVANTAGE COMPARED TO THE SMALLER CHEMICAL DRUGS. UNLIKE THE LATTER, PROTEINS CANNOT YET BE ADMINISTERED ORALLY AND USUALLY HAVE TO BE INJECTED. BUT EVEN THEN PROBLEMS CAN ARISE WITH THE NATURAL POTENCY OF PROTEINS. EXOGENOUS ADMINISTRATION RESULTS IN VARYING DRUG CONCENTRATIONS THAT CAN DEVIATE GREATLY FROM THE NATURAL

SITUATION. SYSTEMIC ADMINISTRATION MIGHT EVEN DETRACT FROM LOCAL EFFECTIVENESS, FOR EXAMPLE IN THE INTERACTION OF CELLS OF THE IMMUNE SYSTEM" (right column, page 454). Thus, besides nucleus targeting, protein pharmacokinetics, host immune response would be another concern for ferritin-H therapy because the recited exogenous ferritin-H in the claims encompasses both allogenic and xenogenic proteins.

Therefore, it is incumbent upon applicants to provide sufficient and enabling teachings within the specification for the claimed invention. Although the instant specification provides a review of the diseases that might benefit from the ex vivo study, it is not enabled for its full scope because the skilled artisan could not predictably extrapolate the ex vivo transfected cell study to the in vivo protein therapy. Applicants are reminded that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991). 35 U.S.C. § 112 requires that the scope of the claims must bear a **reasonable correlation to the scope of enablement** provided by the specification to persons of ordinary skill in the art. In re Fisher, 166 USPQ 18, 24 (CCPA 1970). In the instant case, the determination of the *in vivo* effect of exogenous ferritin-H/ligand complex is not predictable given the complex nature of the sickle cell diseases and mode of operation of ferritin-H/ligand complex, hence resulting in a trial and error situation. Here, the general knowledge and levels of skill in the art do not supplement the omitted description, because specific, not general guidance is what is needed. Therefore, the specification fails to provide an enabling disclosure commensurate with the scope of the claims.

The Federal Circuit has stated that:

a specification need not disclose what is well known in the art. See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement.

However, **when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.** It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1005 (CAFC 1997) (emphasis

added).

Thus, it is evident that at the time of the invention, the skilled artisan, while acknowledging the significant potential of ferritin-H, still recognized that such therapy was neither routine nor accepted, and awaited significant development and guidance for its practice. However, the teachings and guidance present in the specification, as a whole, represent an initial investigation into the feasibility of the development of a useful means for executing ferritin-H therapy which awaits further development to the practical level.

Accordingly, in view of the quantity of experimentation necessary to determine the parameters for achieving *in vivo* gene expression at therapeutic levels, in particular for the treatment of any and all diseases reviewed by the specification, the lack of direction or guidance provided by the specification as well as the absence of working examples with regard to therapeutic regimens, and the breadth of the claims directed to

the delivery of ferritin-H peptide, it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

Conclusion

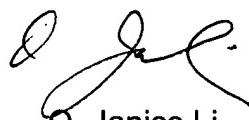
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).



Q. Janice Li
Examiner
Art Unit 1632

QJL
July 14, 2003